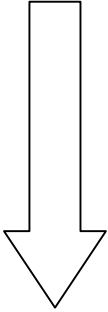


TRANSLATIONAL RESEARCH FUND PROGRAM

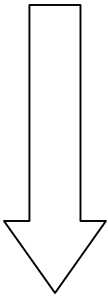
(February 2003)

LOI reviewed at
weekly CTEP/IDB
meeting...

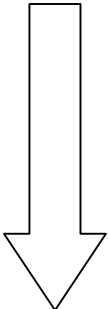
If Correlative Study
Support is ultimately
APPROVED...



SAIC-Frederick, Inc
Solicitation is Sent to
Institution's Business
Office



Contract Awarded



Work Performed
and Invoices Paid

- TRF support must be requested at LOI stage only; LOI must include preliminary budget and justification, using the cost estimate worksheet.
- CTEP reviews the LOI and provides two Priority Scores
 - **LOI Review Criteria**
Strong scientific hypothesis; Not duplicative; Supporting preliminary data and/or a strong rationale; Adequate patient accrual; Innovative correlative studies; Agent availability; Industry sponsor concurs; Ability to meet regulatory requirements; in 2002 1/3 of LOIs for early clinical trials with CTEP IND agents were approved (solicited and unsolicited)
 - **Correlative Studies for TRF Support Review Criteria**
Importance of proposed correlative hypothesis for further development of agent; Biologic rationale for studying the target effect; Relevant preclinical data behind hypothesis; Rationale for selection of assay; Technical performance characteristics of assay; Investigator experience with the assay; Comparability of results with other published data; Impact on future studies; Statistics for data analysis - prevalence of target, study power for chosen end point
- If Correlative Studies score warrants TRF support:
 - The LOI approval letter provides details of discussion, and the plans for the SAIC-Frederick, Inc. contract to support the correlative studies; a draft budget must be included in the LOI or will be requested at this time. Justification should be provided:
 - Personnel effort appropriate and reasonable (PI support very limited)
 - Supplies
 - Shared Resource Costs
 - No Equipment or Travel costs
 - Equipment maintenance/service costs if appropriately justified
 - No costs associated with the development of new assays/technologies
 - No indirect costs may be applied to patient care costs
 - The LOI approval letter requests that the **Protocol be submitted to PIO**, and indicates that SAIC-Frederick, Inc. will be forwarding a **Solicitation, following receipt of the protocol at the PIO.**
 - At this point in the process, the **PI should alert the institution's business office** that a solicitation from SAIC-Frederick, Inc. will be coming.
- The SAIC-Frederick, Inc. technical project officer contacts the correlative studies PI to obtain information regarding current trial status, and accurate contact information for the contract PI and for the institution's business office. Additional information regarding the level of CTEP funding may also be discussed.
- The SAIC-Frederick, Inc. solicitation is forwarded to the institution's business office. The solicitation will include the Statement of Work to be reviewed, and will request a detailed cost estimate/budget and justification.
- The institution submits the proposal to the SAIC-Frederick, Inc. contracting officer who then negotiates the "cost reimbursement" contract. Final approval is granted by CTEP.
- Correlative studies are completed by the awarded institution. Once costs are incurred, either per sample (lab assays) or per patient (imaging study), an invoice is submitted to SAIC-Frederick, Inc. with all accompanying documentation, as outlined in the solicitation. Payment is made after invoices are submitted and after deliverables are confirmed, no more frequently than monthly. Additional details are included in the solicitation.
- Deliverables include CDUS data entry and interim/annual data reports. Before payment can be made, the SAIC-Frederick, Inc. technical project officer checks the CDUS database to be sure that documentation exists for the completion of the correlative study/assay being billed for – this is the primary "deliverable" of the contract. The second deliverable is reporting to CTEP the actual data from the studies – either by submission of the non-competitive continuation for Phase II N01 contracts/U01 awards, or submission of interim/annual reports. Additional details regarding deliverables are included in the solicitation.